

Application No.: 10/729,046

Docket No.: 22956-235

**REMARKS****Status of the Claims**

Claims 1-6, 8-13, 20 and 23-27 are pending in the present Office Action, with claims 1 and 20 being independent claims. Claims 7, 14-19, 21, and 22 are currently withdrawn. Reconsideration of the pending claims is cordially requested.

**Novelty**

Claims 1-10, 20 and 23-25 currently stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 6,110,212 (Gregory). Gregory, however, cannot anticipate these claims because the reference does not disclose a tissue implant comprising a biological tissue slice dimensioned so that the cells of the tissue slice can migrate out of the tissue slice to proliferate and integrate with tissue at the injury or defect, as recited in the claims.

Claim 1 is directed toward a biocompatible tissue implant comprising a biological tissue slice that includes an effective amount of viable cells. The tissue slice is dimensioned so that the cells can migrate out of the tissue slice to proliferate and integrate with other tissue.

Gregory cannot anticipate claim 1 because the reference does not disclose using a biological tissue slice. Gregory is directed the use of an elastin or elastin-based biomaterial, which may be configured as a sheet, and may be used in tissue replacement or repair. Elastin, however, is not a tissue. As noted in Gregory, elastin is an extracellular matrix protein that imparts strength, elasticity, and flexibility in skin, blood vessels, and tissues of the lung (see Gregory, column 1, lines 18-21). Thus, elastin is a component of the extracellular matrix of a tissue, but is distinct from tissue itself.

Though the Office Action refers to elastin or elastin-based biomaterial formed into a three dimensional structure that may be populated with stromal cells, growth factors, and regulatory factors (see *id.*, column 3, lines 22-29), this is not a "biological tissue slice" as recited in claim 1. As discussed in Gregory and the associated U.S. patents cited therein (see *id.*, column 3, lines 29-35), these are stromal cell systems that are man-made, artificial constructs – not biological tissue.

Furthermore, Gregory in no way discusses the use of a slice of biological tissue dimensioned so that cells of the tissue slice can migrate out of the slice as recited in claim 1. To the extent that Gregory discusses the use of a sheet of biomaterial (see *id.*, column 5, lines 52-

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62), the sheet configuration discussion only pertains to the elastin or elastin-based sheet, not to any tissue that is used as a tissue implant. FIGS. 1 and 2 of Gregory depict the use of a sheet of elastin material that is bound to native tissue, or onto an artery. Gregory does not disclose or suggest in any way that the sheet is a tissue slice. As well, no discussion or suggestion of a tissue slice dimensioned so that cells can migrate from the slice is present within Gregory.

Thus, claim 1 is patentably distinct from Gregory. Claims 2-6 and 8-10 depend from claim 1, and therefore distinguish over Gregory for the same reasons, among others.

Claims 2 and 3 further distinguish over Gregory. Since Gregory does not teach the use of a tissue slice as a part of a tissue implant, the reference also lacks the teaching of utilizing autogeneic tissue, allogeneic tissue, xenogeneic tissue, or combinations thereof, as recited in claim 2. Gregory also fails to disclose using the a specific tissue type as selected from the group consisting of cartilage, meniscus, tendon, ligament, intestinal, stomach, bladder, alimentary, respiratory, genital, liver, dermis, synovium, and combinations thereof, as recited in claim 3. Thus, claims 2 and 3 distinguish over Gregory for these reasons as well.

Claims 4-6 are also further distinguished over Gregory. Since Gregory fails to teach the use of a tissue slice, the reference does not indicate any particular thickness that a tissue slice may have, as recited in claims 4-6. As discussed earlier, Gregory only reveals an elastin or elastin-based sheet of biomaterial, not a biological tissue slice having a particular dimension. Thus, claims 4-6 are distinguished from Gregory for these reasons as well.

Claim 20 is a method claim directed to repairing a tissue injury or defect that includes the element of "providing a biocompatible tissue implant comprising a biological tissue slice . . . dimensioned so that the cells can migrate out of the tissue slice." The claim is patentable over Gregory for the reasons stated above for claim 1. Claims 23-25, depending from claim 20, are also patentable over Gregory for the same reason that claim 20 is novel, among others.

### Nonobviousness

Claims 11-13, 26 and 27 currently stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gregory in view of U.S. Patent 6,773,458 B1 (Brauker et al). These claims, however, are not obvious because neither Gregory nor Brauker teach the recited element of a biological tissue slice dimensioned so that the cells can migrate out of the tissue slice.

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Independent claims 1 and 20 recite a biocompatible tissue implant comprising "a biological tissue slice having a geometry suitable for implantation at the tissue site . . . [and] dimensioned so that the cells can migrate out of the tissue slice." As discussed herein, Gregory fails to provide the required teachings to anticipate these claims. Brauker fails to provide any additional teachings to remedy this deficiency of Gregory. Brauker is directed to implant systems and methods that contain implant cells and a chamber that forms a "boundary between the biological system of the host tissue living outside the chamber and the biological system of the implant tissue cells living within the chamber" (see Brauker, column 7, lines 45-49). The implant cells may take a variety of forms including minced lung tissue broken into 5-10  $\mu$ l sized segments (see *id.*, column 13, lines 50-63).

Brauker presents no teaching or suggestion that a biological tissue slice having a geometry suitable for implantation is utilized in its implant teachings. Brauker instead utilizes minced tissue pieces that are encapsulated in test membranes of a suitable geometry (see *id.*). Thus, Brauker also fails to teach a tissue slice "dimensioned so that cells can migrate out of the slice to proliferate and integrate with tissue" at the injury or defect, as recited in claims 1 and 20.

Furthermore, no motivation exists to combine Gregory and Brauker because the latter reference teaches away from dimensioning a tissue slice so that cells of the slice can migrate out of the slice. Brauker is directed to using a barrier to contain the implant cells that is "impermeable to the vascular structure that forms close to the boundary" (see *id.*, column 9, lines 43-44). As implied by Brauker, the pores of the boundary must be sufficient to prevent the implant cells from entering the host (see *id.*, from column 9, line 51 to column 10, line 14). Thus, Brauker teaches away from a tissue implant having a biological tissue slice "dimensioned so that cells can migrate out of the slice to proliferate and integrate with tissue." Indeed, combining Gregory and Brauker would suggest a device or method that isolates a biocompatible elastin structure from the tissue of an implant site.

Thus, the combination of Gregory and Brauker does not render either claim 1 or 20 obvious. Claims 11-13, depending from claim 1, are thus nonobvious for at least the same reasons. Claims 26 and 27, depending from claim 1, are also nonobvious for the same reasons, among others.

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**CONCLUSION**

In view of the remarks above, Applicant submits that claims 1-6, 8-13, 20 and 23-27 are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

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Respectfully submitted,

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